Roma ethnicity and outcomes of coronary artery disease

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Chapter 2

Data sources, measures and statistical analyses

This study was based on data collected within the project 'Social class and its impact on patients' functional status and recovery process - 2009' (No. 275/2009-LF) and its precursor, the project 'Social class and its impact on a patients' functional status and recovery process after cardiological or cardiosurgical intervention'. Both projects were carried out as interdisciplinary studies and were based on cooperation between the University of Groningen in the Netherlands, the Pavol Jozef Safarik University in Kosice and the East Slovakian Institute of Cardiac and Vascular diseases in Kosice, Slovakia. The aim of these projects was to explore the impact of socioeconomic status and Roma ethnicity on health differences among patients undergoing coronary angiography (CAG) and cardiological intervention or cardiac surgery in East Slovakia. The psychosocial aspects and health-related quality of life in coronary artery disease (CAD) patients were studied previously by Skodova (1) and Silarova (2). This chapter provides a general overview of the study population, data collection, measures and statistical analyses.

2.1 Study population and data collection

These projects were conducted in the East Slovakian Institute for Cardiac and Vascular Diseases in Kosice, Slovakia, from November 2004 until June 2013. This institute is one of the three tertiary centers in Slovakia specialized for the diagnostics and treatment of cardiac and vascular diseases, serving primarily the region of East Slovakia, with approximately 1.5 million inhabitants. Patients were referred here by their cardiologist or physician for CAG in cases of suspected or diagnosed CAD for diagnosis and further treatment according to valid European Society of Cardiology guidelines.

Inclusion and exclusion criteria for baseline examination were defined as follows:

Inclusion criteria:

- CAD in the medical history of the patient;
- Age 75 years or less;
- Signed informed consent.

Exclusion criteria:

- Cardiac diseases other than chronic forms of CAD (e.g. acute coronary syndromes, including acute myocardial infarction, severe valve disease, severe atrial or ventricular septal defects, pericarditis or myocarditis, cardiomyopathies other than ischaemic, pulmonary embolism);
- Severe cognitive impairments (e.g. dementia, mental retardation) or psychiatric disorders in the medical history (e.g. depression, bipolar disorder, schizophrenia);
- Severe comorbidity (e.g. malign tumors, dialysed patients, nervous system diseases).

Data collection consisted of two measurements: a baseline measurement T0 (the day preceding the CAG) and a follow-up examination T1 (12-26 months later). During the baseline measurement, extraction of data from medical records and a physical examination, including blood pressure and heart rate measurements, were performed by a cardiologist. A psychologist or trained research assistant conducted an interview with each participant. Patients were invited for a follow-up examination via postal mail. During the follow-up the same type of interview as at the time of enrollment was conducted, as well as a physical examination of the patient, with extraction of data from medical records performed by a cardiologist.

Between November 2004 and June 2013 approximately 20,000 patients scheduled to undergo CAG satisfied the inclusion criteria for this project, and 1010 consecutive patients were asked to participate in the study. We stratified them by SES, measured by educational level and then sampled per stratum to obtain equal numbers of these categories per stratum. A total of 41 (4.2%) refused to participate (response rate 95.9%) and 92 (9.1%) were excluded based on the exclusion criteria.

Out of those included, 254 (25.1%) patients had a normal CAG, 20 (7.9%) of whom were Roma. Thus, the population at baseline consisted of 623 patients, 103 of whom were Roma. As the five articles (Chapter 3 – 7) used in this thesis were written at different times during data collection, different populations are used in these chapters. The numbers concerned are shown in Table 2.1. In the first two articles another 82 Roma patients, whose data were collected in the years 2001-2003, before these projects started, were included.

The study was approved by the Ethics Committee of the East Slovakian Institute for Cardiac and Vascular Diseases in November 2004. All participants were provided with information about the study and voluntarily signed an informed consent statement prior to the study. The study was performed according to the Declaration of Helsinki.

Table 2.1 Description of the study population as used in the chapters

Study population	Chapter 3	Chapter 4	Chapter 5	Chapter 6	Chapter 7
Study design	cross-sectional	longitudinal	longitudinal	longitudinal	longitudinal
Data collection	674 patients measured at baseline	816 patients measured at baseline and follow-up	832 patients measured at baseline and follow-up	623 patients measured at baseline and follow-up	264 patients measured at baseline and follow-up
Follow-up		Up to 7 years	Up to 8 years	Up to 9 years	12-26 months
Time period	2001-2010	2001-2011	2004-2012	2004-2013	2004-2013
Roma (n, %)	132 (19.6%)	167 (20.5%)	110 (13.2%)	103 (16.5%)	25 (9.5%)

2.2 Measures

We obtained data on sociodemographic background, clinical status, self-rated health (SRH) and all-cause mortality during the interview with the patient, physical examination or from medical records.
Sociodemographic data included age, gender and educational level. Educational level was classified into three categories – low (elementary school or secondary school without school leaving exam), middle (secondary school with school leaving exam) and high (university degree). Ethnicity was measured based on each patient's declaration and identification by the doctor. In case of conflicting opinions, an independent third person (a head nurse) was decisive.

Clinical data were retrieved from the medical records. These included disease history, use of drugs and type of treatment after CAG. Disease history concerned previous myocardial infarction, arterial hypertension, diabetes mellitus and dyslipidaemia. The functional status of the patient was assessed using the Canadian Cardiovascular Society (CCS) and New York Heart Association (NYHA) functional classifications (Tables 2.2 and 2.3). The CCS identifies the severity of chest pain in 4 classes (3), and the NYHA classifies dyspnea symptoms in 4 classes (4,5). In both scales, a higher score represents worse symptomatology. Regarding the use of drugs, we collected data about the most commonly used cardiovascular drugs, like acetylsalicylic acid (ASA), clopidogrel, beta-blockers, angiotensin converting enzyme inhibitors, statins, nitrates, anxiolytics and non-steroid anti-inflammatory drugs (NSAIDs). We also asked about smoking status (smoker or non-smoker) and alcohol use (alcohol consumption yes or no). Based on a physical examination of each patient, body mass index (BMI), systolic and diastolic blood pressure and heart rate were registered. Levels of total, low-density lipoprotein (LDL) and high-density lipoprotein (HDL) cholesterol and triglycerides were registered according to laboratory findings. The ejection fraction was measured by ultrasound using either the Simpson method or estimated by the occulometric method. Moreover, we obtained data on coronary findings from CAG.

Table 2.2 Canadian Cardiovascular Society Functional Classification (3)

Class I	Ordinary physical activity does not cause angina, such as walking and climbing stairs. Angina with strenuous or rapid or prolonged exertion at work or recreation.
Class II	Slight limitation of ordinary activity. Walking or climbing stairs rapidly, walking uphill, walking or stair climbing after meals, or in cold, or in wind, or under emotional stress, or only during the few hours after awakening. Walking more than two blocks on the level and climbing more than flight of ordinary stairs at a normal pace and in normal conditions.
Class III	Marked limitation of ordinary physical activity. Walking one to two blocks on the level and climbing one flight of stairs in normal conditions and at normal pace.
Class IV	Inability to carry on any physical activity without discomfort – angina syndrome may be present at rest.

Table 2.3 New York Heart Association functional classification based on severity of symptoms and physical activity (4)

Class I	No limitation of physical activity. Ordinary physical activity does not cause undue breathlessness, fatigue, or palpitations.
Class II	Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class III	Marked limitation of physical activity. Comfortable at rest, but less than ordinary physical activity results in undue breathlessness, fatigue, or palpitations.
Class IV	Unable to carry on any physical activity without discomfort. Symptoms at rest can be present. If any physical activity is undertaken, discomfort is increased.

The type of treatment following the CAG concerned conservative pharmacological treatment, percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG). This was decided on by cardiologists based on the results of CAG and the patient's clinical status, independently of participation in this study. The severity of the CAD was evaluated using the CCS and NYHA functional classifications and by the number of diseased coronary vessels found in the CAG, e.g. one-vessel, two-vessel or three-vessel disease.

Self-rated health (SRH) was measured using the first question of the Short Form Health Survey (SF-36) (6). The validity and reliability of the SF-36 scale have been established in patients with coronary artery disease (7).

Data on patient mortality after CAG were obtained from the Central Registry of the Health Care Surveillance Authority of the Slovak Republic. This authority registers on its web based portal the status of the health insurance of each citizen of the Slovak Republic. After identification of the patient according to his or her specific birth number, it gives answers the question of whether a person is currently insured or not. If not, it gives a more specific answer – either the health insurance is currently not valid or the patient died. In that case the date of death is given.

2.3 Statistical analyses

Statistical analyses were performed using the statistical software program PASW SPSS version 16.0.1, 18.0 and 20.0 for Windows (SPSS Inc., Chicago, Illinois, USA) and the statistical program Mplus 7.1 (Muthen&Muthen, Los Angeles, USA). First, the sociodemographic and clinical characteristics of the studied populations were described. Differences were statistically tested using the t-test or Mann-Whitney U-test for continuous variables and χ^2 or Fisher exact tests, when appropriate, for categorical variables. Values of $p<0.05$ were considered to be statistically significant. Changes over time were tested using paired t-tests or related-samples Wilcoxon signed rank tests for continuous variables and χ^2 square tests or McNemar tests for categorical variables, as appropriate (Chapter 4). Then linear and logistic regression analyses, with adjustments for age, gender and education, were performed in order to assess the effect of ethnicity on the outcome variables (Chapters 3, 4). Kaplan-Meier curves of mortality were plotted, and log-rank tests between Roma and non-Roma patients were computed in Chapters 5 and 6. Hierarchical Cox regression models explored the effect of ethnicity and SRH on mortality (Chapters 5, 6, 7). Possible mediation between ethnicity and self-rated health was tested according to Baron and Kenny (Chapter 7) (8).

References

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(4) McMurray JJ, Adamopoulos S, Anker SD, Auricchio A, Bohm M, Dickstein K, et al. ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012: The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European